

REMARKS

This is a response to the Office Action mailed September 21, 2005. Claims 1, 3, 5-7, 10-32, 37-39, 41-44, 46-50, 53-59, 61 and 63-82 are pending in the application. Claims 1, 3, 5-7, 10-32, 37-39, 41-44, 46-50, 53-59, 61 and 63-85 have been rejected by the Examiner.

Claim Rejections – 35 U.S.C. § 102

The Examiner has rejected Claims 1, 3, 5-7, 10-16, 21-32, 37-39, 46-50, 53-59, 61 and 63-85 under 35 U.S.C. §102(a) as being anticipated by U.S. Patent No. 6,296,603 to Turnlund et al. (“Turnlund”). U.S. Patent No. 6,296,603 was filed on May 26, 1998.

Turnlund teaches that a stent graft may be configured to irradiate **different levels** of radiation longitudinally and/or circumferentially along the stent (Col. 10, lines 36-38). Turnlund also teaches that the stent graft, having a uniform radioactivity longitudinally therealong, **will not emit a uniform dose rate of radiation near the proximal and distal ends, as compared to the center of the stent graft** (Col. 10, lines 42-47). Further, Turnlund teaches the proximal and distal end portions of the stent which anchor the stent to the vessel may have **different activities** as compared to the growth inducing radioactivity of the central portion of the stent to limit potentially occlusive in-growth at the proximal and distal ends of the stent graft (Col. 10, lines 51-55).

Turnlund fails to teach an elongated source that has a concentration of a therapeutic agent that **gradually decreases along the length of the elongated source from a point inward of a proximal end to or near the proximal end of the elongated source**, as recited in independent Claim 1 of the present invention.

Further, Turnlund fails to teach an elongated radiation delivery source including a radioactive region, where the radioactive region includes a segment **“gradually transitioning from the therapeutic level to a non-therapeutic level of radioactivity”** as recited in

independent Claim 6, or a method of producing such a radioactive delivery source as in independent Claim 13.

Further, Turnlund fails to teach a stent including a radioactive region along the length of the stent, and the radioactive region includes “a radioactive **gradient near a proximal end or a distal end of the radioactive region, the radioactivity gradient gradually decreasing the dose delivered to the vessel from a therapeutic level to a non-therapeutic level of radioactivity**” as recited by independent Claim 21.

Further, Turnlund fails to teach a stent having a “**drug concentration gradient gradually decreasing from a therapeutic dose level to a non-therapeutic dose level**” as recited by independent Claim 31.

Further, Turnlund fails to teach a method of producing a drug source by “**gradually transitioning the drug concentration from the therapeutic level of drug concentration to a non-therapeutic level,**” as recited in independent Claim 37.

Still further, Turnlund fails to teach a stent where the concentration or amount of therapeutic agent **gradually changes by incremental segments along the length of the stent or at a constant rate** as in independent Claim 46, or a method of producing such a stent, as recited in Claim 53.

In contrast, Turnlund teaches the stent graft may be configured to irradiate **different levels** of radiation longitudinally along the stent (Col. 10, lines 36-38). That the proximal and distal end portions of the stent in Turnlund have **different activities** as compared to the inducing radioactivity of the central portion of the stent does not disclose **gradually decreasing, gradual transitioning, or gradual changing** the therapeutic level or level of radiation as recited in the independent Claims 1, 6, 13, 21, 31, 37, 46, and 53 of the invention. In fact, irradiating different levels of radiation longitudinally along the stent is the complete opposite of irradiating gradually along the length of the stent. The Office Action suggests that Figure 6 of Turnlund teaches a

gradual decrease of amount of radiation along the length of the stent-graft from a point inward of a proximal portion to near the proximal end of the stent-graft and as well as from a point inward of a distal portion to near the distal end of the stent-graft (Page 3). However, Turnlund illustrates a stent-graft having a radioactivity dose profile that includes sharp transitions at 0.1 mm out from the stent surface from high radioactivity of over 35,000 cGy to low radioactivity of below 15,000 cGy along the length of the Turnlund stent-graft in Figure 6 (Col. 9, lines 61-Col. 10, lines 1-4). The sharp transitions from high radioactivity illustrated in Figure 6 is clearly opposite from **gradually decreasing**, **gradually transitioning**, or **gradually changing** radiation, as recited in the claims of the present application. Because Turnlund teaches **different levels** of radiation being irradiated longitudinally along the stent, not **gradual levels** of radiation longitudinally along the stent as recited in independent Claims 1, 6, 13, 21, 31, 37, and 53, Turnlund fails to teach each and every element of independent Claims 1, 6, 13, 21, 31, 37, and 53 and the claims dependent thereon.

With respect to independent Claims 63, 65, 67, 69, 70, and 71, Turnlund fails to teach a stent, a method of forming a coating on a stent, or a method of producing a stent having a drug. There is nothing in Turnlund that teaches or even suggests use of a drug or a coating of the drug on a stent. In contrast, Turnlund teaches that, “the proximal and distal portions of the stent which anchor the stent to the vessel may have different activities as compared to the growth inducing **radioactivity** of the central portion of the stent” (Col. 10, lines 52-56). Use of “radioactivity” on the stent-graft to increase the rate of thrombus formation and/or proliferative cell growth is not the same as the use of drugs on a stent. Applicants respectfully submit that Turnlund falls very short of even remotely teaching that which has been claimed by claims 63, 65, 67, 69, 70, and 71.

Since Turnlund fails to teach all the limitations of the independent Claims 6, 13, 21, 31, 37, 53, 63, 65, 67, 69, 70, 71, and the claims dependent thereon, the Claims are in condition for allowance.

Claim Rejections – 35 U.S.C. § 103

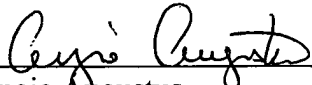
Claims 17-20, 41-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Turnlund. As noted above, Claim 13 is allowable over Turnlund, and because Claims 17-20 depend directly or indirectly from Claim 13, Claims 17-20 are allowable for at least the same reasons. Also, as noted above, Claim 37 is allowable over Turnlund, and because Claims 41-44 depend directly or indirectly from Claim 37, Claims 41-44 are allowable for at least the same reasons.

CONCLUSION

Claims 1, 3, 5-7, 10-32, 37-39, 41-44, 46-50, 53-59, 61 and 63-82 are pending in the application. Allowance of the claims is respectfully requested. If I can be of any help in anyway, please contact me.

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Respectfully submitted,



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